DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 16, 2015

Edwards Lifesciences LLC
Ms. Nina Brooke
Regulatory Affairs Associate III
One Edwards Way
Irvine, California 92614

Re: K141206
Trade/Device Name: ThruPort Knotting Instrument
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: Class II
Product Code: GAW, HCF
Dated: January 12, 2015
Received: January 14, 2015

Dear Ms. Brooke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141206

Device Name
ThruPort Knotting Instrument

Indications for Use *(Describe)*

The knotting instrument used in conjunction with 2-0 polyester or 2-0 polypropylene suture and a knot loader with nitinol knot is indicated for use in the approximation of soft tissue and prosthetic materials.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary K141206

Submitter: Edwards Lifesciences LLC

Contact Person*:* Nina Brooke, Regulatory Affairs Associate III
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Date Prepared: January 15, 2015

Trade Name: Edwards ThruPort OptiClip Knotting System

Classification Name*:* Suture, Nonabsorbable, Synthetic, Polypropylene (21 CFR §878.5010, Product Code GAW, Class II)

Instrument Ligature Passing and Knot Tying, General & Plastic Surgery Panel (21 CFR §878.4800, Product Code HCF, Class I)

Predicate Device: K100593, Suture Placement Devices and Accessories, LSI Solutions, Inc.

Device Description:

Edwards Lifesciences' ThruPort OptiClip Knotting System is a sterile, non-pyrogenic, single-use surgical instrument made of metal and polymeric materials. It consists of the ThruPort OptiClip Knotting Instrument and the ThruPort OptiClip Knot Loader.

Intended Use:

Intended for use in the approximation of soft tissue and prosthetic materials.

Indications for Use:

The ThruPort Knotting Instrument is used in conjunction with 2-0 polyester or 2-0 polypropylene suture and a knot loader with nitinol knot and is indicated for use in the approximation of soft tissue and prosthetic materials.

Comparative Analysis:

The subject device has the same intended use and technological characteristics (i.e., design, material, chemical composition) as the predicate device. It has been demonstrated that the subject device is comparable to the predicate device in fundamental scientific technology, material types, principles of operation, and functional performance evaluations.

Functional and Safety Testing:

The functional data indicate that the device performs in a substantially equivalent manner when compared to the predicate device. The following functional tests were completed and all results met acceptance criteria:

- **Functional bench testing (design verification)**
  - **Knot Loader Suture Snare Tensile Strength**: Demonstrate that the Knot Loader suture snare can withstand forces encountered during suture loading within the Knotting Instrument.
  - **Knotting System Suture Loading Force**: To establish the forces encountered during suture loading within the Knotting Instrument
  - **Knotting Instrument Shaft Stiffness**: Demonstrate that the shaft of the Knotting Instrument has adequate stiffness to perform effectively within the intended use.
  - **Knotting Instrument Weight**: Demonstrate that the weight of the assembled Knotting System allows for adequate tactile feedback.
  - **Dimensional Interference**: Demonstrate that the components of the Knotting System (including the un-deployed nitinol knot) do not exhibit dimensional interference relative to the suture prior to deployment.
  - **Pinch Point Area**: Demonstrate that the area of the exposed Knotting System pinch point is less than that of the predicate device.
  - **Knotting Instrument Effective Length**: Demonstrate that the effective length of the 15cm, 22cm, and 30cm Knotting Instrument are as labeled
  - **Shaft Outer Diameter**: Demonstrate that the outer diameter of the Knotting Instrument is less than or equal to the predicate device.
  - **Overall Nitinol Knot Height**: Demonstrate that the deployed nitinol knot height is less than or equal to the predicate device
  - **Knot Loader Outer Diameter**: Demonstrate that the outer diameter of the Knot Loader is less than or equal to the predicate device outer diameter.

- **Knotting System Deployment Force**: Demonstrate that the force required to fully depress the trigger and deploy a nitinol knot exceeds the weight of the Knotting System and is low enough to ensure ease of use
- **Suture Tension**: Demonstrate that the tension required to cut suture is less than or equal to the predicate device.
- **Knot Loader Disposable Tip Push Off Force**: Demonstrate that the Knot Loader locking tip will not be pushed off during the deployment of the nitinol knot.
- **Nitinol Knot Push Off Force**: Demonstrate that the Knot Loader locking tip will not be pushed off during the deployment of the nitinol knot.
- **Nitinol Knot Suture Retention Strength**: Demonstrate that the nitinol knot can effectively secure the suture upon deployment when used for the intended use.
- **Knotting Instrument Handle Strength**: Demonstrate that the handle of the Knotting Instrument can withstand the force of applying suture tension and pressure onto tissue or prosthetic material.
- **Knotting Instrument Corrosion**: Demonstrate that the Knotting Instrument can function after exposure to a simulated use environment.
- **Nitinol Knot Corrosion**: Demonstrate that the nitinol knot does not corrode.
- **Knotting Instrument Durability**: Demonstrate that the Knotting Instrument can function for a maximum of 25 deployment cycles.
- **Knotting System Packaging Integrity**: Demonstrate that the packaging configuration of the Knotting System is able to maintain a sterile barrier after worst case conditioning.
- **Nitinol Knot Magnetic Resonance Conditional Testing**: To substantiate the claim of magnetic resonance (MR) conditional.

• **Biocompatibility testing** was performed per ISO 10993-1:2009

• **Sterility and sterile barrier testing**

• **Shelf life testing**

• **Packaging testing**

• **Design validation**

MR evaluation testing:

Per testing conducted the following MR safety statement will be added to our labeling

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the nitinol knot is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial gradient magnetic field of 3,000 Gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the nitinol knot is expected to produce a maximum temperature rise of less than 1.5 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the nitinol knot extends approximately 1 mm from the nitinol knot when imaged with a spin echo pulse sequence in a 3.0 T MRI system and 5 mm from the nitinol knot when imaged with a gradient echo pulse sequence in a 3.0 T MRI system.

The **knotting instrument** and **knot loader** are MR Unsafe.

A patient identification card is included with the **knot loader,** which contains the MRI safety information for the nitinol knot. Fill out the patient specific information including patient name, date of implant, doctor name, and doctor phone number and then distribute to the patient at discharge.

Conclusion:

The Edwards Thruport OptiClip Knotting System is substantially equivalent to the cited predicate device. Additionally, the device testing confirms the safety and effectiveness of the device when compared to the predicate device.